APPENDIX A — EXCERPTED ALPHAPHARM'S MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' REQUEST FOR ATTORNEYS' FEES DATED APRIL 28, 2006

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Civil Action No.
03 CV 8253 (DLC)

Takeda Chemical Industries, Ltd., and
Takeda Pharmaceuticals North America, Inc.,

Plaintiffs,

v.

Mylan Laboratories, Inc.,
Mylan Pharmaceuticals, Inc., and
UDL Laboratories, Inc.,

Defendants.

Civil Action No.
04 CV 1966 (DLC)

Takeda Chemical Industries, Ltd., and
Takeda Pharmaceuticals North America, Inc.,

Plaintiffs,

v.

Alphapharm Pty. Ltd., and Genpharm, Inc.,

Defendants.

Appendix A

ALPHAPHARM'S MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' REQUEST FOR ATTORNEYS' FEES

* * *

Next, Alphapharm respectfully directs the court to a very important opinion espoused by Dr. Mosberg. Dr. Mosberg believed that the skilled artisan would have had a reasonable expectation of successfully obtaining a better drug—not necessarily a blockbuster drug (something the law does not require)—through the routine optimization steps of "ring-walking" and homologation. Dr. Mosberg told Alphapharm his opinion. He expressed it in his expert report. And he testified about it in his trial declaration.

Opinion

> The skilled artisan could reasonably expect success in achieving a better drug through the optimization steps of ring walking and homologation.

Expert Report

> "[Ring walking or] variation in substituent position is routine in drug discovery, since such changes often lead to improvements."[50]

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50. Ex. U, 7/15/05 Mosberg Ex. Rpt. at 11.

"'[H]omologation' [ ] is a standard approach in drug design, especially when attempting to 'fine tune' a successful lead compound, since small structural changes often result in significant efficacy improvements."[51]

Trial Declaration

"One skilled in the art of medicinal chemistry would have been motivated to 'tweak' the 6 methyl to maximize its effectiveness by altering the position of the methyl on the pyridyl ring ('walking the methyl around the ring') and by substituting an ethyl (C_2H_5) for the methyl in the available positions on the pyridyl ring . . . **Though there is no absolute predictability in the field of medicinal chemistry**, any person of ordinary skill in the art would have had a ***reasonable expectation of success*** in 'tweaking' the lead compound in this way."[52]

* * *

A. Alphapharm Used the Discovery Process to Hone the Positions Advanced in the Notice

Alphapharm used the discovery process to: 1) support its theories of invalidity, and 2) rebut

51. *Id.* at 12.

52. Ex. C 11/18/05 Trial Decl., at ¶29.

Takeda's. Alphapharm never used discovery to "fish" around for new theories. During expert discovery, for example, Alphapharm determined that the failure of Takeda to reveal the '605 and '779 patents would have had a substantial impact on the Examiner, because the prior art had not "taught away" from the six-methyl. In fact, Takeda specifically claimed that compound after Sohda II published.[56] And Takeda noted that the six-methyl had become ***especially important*** in the file history.[57] Any reasonable litigant would have made same arguments. ***Prior art must be viewed as a whole.*** *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (references must be viewed as a whole and not in isolation of one another). It would have been negligent for Alphapharm's counsel to ignore these references once Takeda adopted the position that Sohda II "taught away" from compound 58.

* * * *

56. Ex. M at claim 4.

57. Ex. P, '779 file history, July 7, 1982 Preliminary Amendment, alpha-54 (emphasis added).

APPENDIX B — EXCERPTED CORRECTED BRIEF FOR DEFENDANTS-APPELLANTS ALPHAPHARM PTY., LTD. AND GENPHARM, INC. DATED FEBRUARY 11, 2008

Appeal Nos. 07-1269, -1270

United States Court of Appeals

for the

Federal Circuit

TAKEDA CHEMICAL INDUSTRIES, LTD. and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Plaintiffs-Appellees,

– v. –

MYLAN LABORATORIES, INC., MYLAN PHARMACEUTICALS, INC. and UDL LABORATORIES, INC.,

Defendants-Appellants,

– and –

ALPHAPHARM PTY., LTD. and GENPHARM, INC.,

Defendants-Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK IN CASE NO. 04-CIV-1966, JUDGE DENISE COTE

CORRECTED BRIEF FOR DEFENDANTS-APPELLANTS ALPHAPHARM PTY., LTD. and GENPHARM, INC.

Appendix B

EDGAR H. HAUG, ESQ.
KEVIN MURPHY, ESQ.
JEFFREY A. HOVDEN, ESQ.
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, New York 10151
(212) 588-0800

Attorneys for Defendants-Appellants Alphapharm Pty., Ltd. and Genpharm, Inc.

February 11, 2008

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* * *

3. The purpose of a Paragraph IV Letter is to provide the patent holder sufficient information to assess whether or not to sue the ANDA applicant. The law does not require the Paragraph IV Letter to contain each and every argument the patent challenger will use at trial. The district court found that Alphapharm committed litigation misconduct because it made arguments, and relied on prior-art references, outside the scope of those presented in its Paragraph IV Letter. Did the district court clearly err?

* * *

Appendix B

SUMMARY OF THE ARGUMENT

Alphapharm's obviousness challenge was not "exceptional" within the meaning of § 285. It was well-founded. The compounds Takeda claimed in the '777 patent reflected nothing more than routine innovation in Alphapharm's view. Takeda made simple substitutions to the most-potent compound in the prior art to reduce that compound's side-effect profile. In good faith, Alphapharm determined that any skilled artisan would have had every reason to make—and could have made—those routine changes. The district court thought otherwise, and found the compounds claimed in the '777 patent nonobvious. But Alphapharm's failure to convince the district court by clear and convincing evidence does not convert Alphapharm into a bad-faith litigant.

A number of factors—none justified by the record—led the court to assess fees against Alphapharm. Firstly, the district court lowered the bar for an exceptional-case finding. Rather than requiring Takeda to prove Alphapharm's challenge to the '777 patent presented a gross injustice by clear and convincing evidence, the district court only required a showing of simple negligence. Secondly, the district court misapplied the law of structural obviousness in assessing Alphapharm's good-faith challenge to the claimed compounds. Thirdly, the court erroneously believed that Alphapharm was not entitled to develop its case through discovery. Under that view, any deviation at trial from the allegations presented in Alphapharm's presuit Paragraph IV Letter amounted to a "course shift" and a "search for

obviousness." Finally, the district court appears to have misinterpreted deposition testimony concerning Alphapharm's initial investigation and assumed that Alphapharm arbitrarily granted itself a bifurcation of the attorneys' fees issues. These and other errors converted a routine challenge based on structural obviousness into something sinister in the court's view. The exceptional-case finding must be reversed and the award of attorneys' and expert fees vacated.

ARGUMENT

* * *

B. In Direct Conflict with the Hatch-Waxman Act, the District Court Required Alphapharm to Disclose Every Trial Argument in Its Paragraph IV Letter

In addition to the separate error of requiring Alphapharm to identify compound b as a lead compound, the district court faulted Alphapharm for not identifying each and every reference it later relied on at trial. (JA56; JA59-60; JA70.)

But courts have directly addressed and rejected any requirement that generic drug companies be limited at trial to the content of their Paragraph IV Letters. *See e.g., Pfizer, Inc. v. Teva Pharms. USA, Inc.*, No. 04-754, 2007 WL 4300155, at *7-11 (D.N.J. Dec. 5, 2007) (rejecting Pfizer's argument that Teva's Paragraph IV Letter was submitted in bad faith for failing to identify

prior-art references relied on at trial). The Paragraph IV Letter need only alert the patentee to the possibility of infringement by the ANDA applicant so that "patent owner can protect its interests in its patents by filing a patent-infringement action." *See Astra Aktiebolag v. Kremers Urban Dev. Co.*, No. 99-8928, 2000 WL 257125, at *1 (S.D.N.Y. Mar. 6, 2000). Here, Alphapharm complied with its statutory requirements and the district court appeared to agree. (JA51.)

Nonetheless, the district court still found Alphapharm's Paragraph IV Letter baseless. Its ruling would have the effect of frustrating the very purposes of the Hatch-Waxman Act, which as demonstrated from its legislative history, was to reduce health-care costs by encouraging early challenges to invalid or unenforceable patents. In 1997, reflecting on the 13-year history of the Act, Senator Hatch noted the Act "continues to provide incentives for drug companies to undertake research on new drugs while enabling low cost, generic equivalents that are relied upon by consumers ***to come quickly to the market***." S. Rep. No. 105-36(I), at 125 (1997) (emphasis added). The House seconded Senator Hatch's sentiment. *See* H.R. Rep. No. 108-181, at 9 (2003) (noting that Title XI, Access to Affordable Pharmaceuticals, "[i]ncorporates text of S. 1225 as adopted by the Senate, which will make lower cost generic drugs available more quickly.").

The district court's decision, if left to stand, would limit ANDA filers to presuit Paragraph IV Letters and would frustrate the incentives to early challenges the

Act envisioned. Generic companies would refrain from attacking invalid patents unless confident the case could be won without pretrial discovery. But ANDA cases are no different from other cases in the federal system. Parties must be afforded a reasonable time to develop facts and refine legal theories. *See, e.g., Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570 (Fed. Cir. 1997) (holding that infringement inquiry not limited to ANDA alone but to other materials challenger submitted to the FDA "and other pertinent evidence provided by the parties"); *Dey, L.P. v. Ivax Pharms., Inc.*, 233 F.R.D. 567, 570 (C.D. Cal. 2005) (holding in ANDA case that discovery entitled defendants to narrow and clarify patentee's position on inventorship). There is no basis in the Hatch-Waxman Act or the caselaw to carve out an exception for ANDA cases.

Indeed, it is axiomatic that positions develop and change during the course of patent litigation, particularly during fact and expert discovery. For example, the district court's ruling would render § 282, which requires a defendant to identify the prior art it intends to rely on ***30 days before trial,*** meaningless. 35 U.S.C. § 282. It would also discourage ANDA applicants from availing themselves of the Federal Rules of Civil Procedure because ANDA applicants would risk attorneys' fees when moving to amend or supplement their pleadings. *See* Fed. R. Civ. P. 15.

Further, allegations of unenforceability are commonly raised ***after*** considerable discovery has been accomplished such that a party can meet the obligations

under Federal Rules of Civil Procedure 9 and 11. To require an ANDA applicant, under penalty of an attorneys' fees sanction, to include every noninfringement, invalidity, and unenforceability argument in a presuit Paragraph IV Letter could never be the law, as this Court has already recognized. *See Q-Pharma, Inc. v. Andrew Jergens Co.*, 360 F.3d 1295, 1304 (Fed. Cir. 2004) (finding case not exceptional despite that patentee changed its infringement theory in the middle of discovery); *see also Aventis Pharma Deutschland GmbH v. Lupin Ltd.*, 409 F. Supp. 2d 722, 728 n.2 (E.D. Va. 2006) (noting that every ANDA filing is essentially "baseless" when the challenger ultimately loses at trial). The district court's ruling turns "exceptional" on its head.

* * * *

APPENDIX C — EXCERPTED CORRECTED REPLY BRIEF FOR DEFENDANTS-APPELLANTS ALPHAPHARM PTY., LTD. AND GENPHARM, INC. DATED JUNE 26, 2008

Appeal Nos. 07-1269, -1270

United States Court of Appeals

for the

Federal Circuit

TAKEDA CHEMICAL INDUSTRIES, LTD. and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Plaintiffs-Appellees,

– v. –

MYLAN LABORATORIES, INC., MYLAN PHARMACEUTICALS, INC. and UDL LABORATORIES, INC.,

Defendants-Appellants,

– and –

ALPHAPHARM PTY., LTD. and GENPHARM, INC.,

Defendants-Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK IN CASE NO. 04-CIV-1966, JUDGE DENISE COTE

CORRECTED REPLY BRIEF FOR DEFENDANTS-APPELLANTS ALPHAPHARM PTY., LTD. and GENPHARM, INC.

Appendix C

EDGAR H. HAUG, ESQ.
KEVIN MURPHY, ESQ.
JEFFREY A. HOVDEN, ESQ.
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, New York 10151
(212) 588-0800

Attorneys for Defendants-Appellants Alphapharm Pty., Ltd. and Genpharm, Inc.

June 26, 2008

* * *

TABLE OF AUTHORITIES

Cases

BMW of N. Am. v. Gore,
517 U.S. 559 (1996) 14

* * *

Indeed, in patent cases, the use of additional prior-art references—and additional theories developed with those references—is expected. As Alphapharm pointed out in the opening brief, the challenger must alert the patentee to ***all*** prior-art references it wil rely on—not at the outset of a case—but within 30 days of trial. *See* 35 U.S.C. § 282. Takeda does not—and cannot—

maintain that a special exception to this provision exists for Hatch-Waxman cases. Yet, the district court sanctioned Alphapharm for its later timely reliance on prior-art references such as U.S. Patents 4,340,605 and 4,444,779.[2] (JA62-63.) Doing so amounts to little more than changing the rules in the middle of the game. *C.f., BMW of N. Am. v. Gore*, 517 U.S. 559, 573 (1996) (prohibiting Alabama jury from imposing punitive sanctions on conduct lawful in other jurisdictions).

* * *

The ruling will also create perverse incentives. The district court chose to sanction Alphapharm for dropping a theory based on what it had learned in discovery (JA57-58)—the very outcome Takeda urged upon the district court in the first instance. (JA175; JA181-82; JA2020-22.) Affirming that ruling will only encourage generic challengers to put in and maintain every possible argument at trial, for fear that narrowing the issues will be used against them in a later fees application.

Nowhere in its Opposition does Takeda address these profound implications, and its silence is deafening. Left to stand, the court's ruling arms the brand-name company with the full use of the broad discovery set forth in the Federal Rules of Civil Procedure while

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2. Alphapharm's § 282 Statement with these references was served on December 15, 2005, more than 30 days before the trial began on January 17, 2006. (A9549-53.)

forcing a generic company to subject itself to sanctions for availing itself of the same Rules. Such a result is clearly contrary to this Court's law. "[T]here is and should be no difference in the standards applicable to patentees and infringers who engage in bad faith litigation." *Eltech Sys. Corp. v. PPG Indus., Inc.*, 903 F.2d 805, 811 (Fed. Cir. 1990). Reversing the district court's ruling will restore a level playing ground. *See Doubleday & Co. v. Curtis*, 763 F.2d 495, 503 (2d Cir. 1985) (reversing dismissal of claim where dismissal "violated the spirit of both the United States Constitution [due process clause] and the Federal Rules of Civil Procedure [Rule 8(c)].").

* * * *

APPENDIX D — EXCERPTED PETITION FOR REHEARING EN BANC FOR DEFENDANTS-APPELLANTS ALPHAPHARM PTY., LTD. AND GENPHARM, INC. DATED DECEMBER 22, 2008

Appeal Nos. 07-1269, -1270

United States Court of Appeals

for the

Federal Circuit

TAKEDA CHEMICAL INDUSTRIES, LTD. and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Plaintiffs-Appellees,

– v. –

MYLAN LABORATORIES, INC., MYLAN PHARMACEUTICALS, INC. and UDL LABORATORIES, INC.,

Defendants-Appellants,

– and –

ALPHAPHARM PTY., LTD. and GENPHARM, INC.,

Defendants-Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK IN CASE NO. 04-CIV-1966, JUDGE DENISE COTE

PETITION FOR REHEARING EN BANC FOR DEFENDANTS-APPELLANTS ALPHAPHARM PTY., LTD. and GENPHARM, INC.

Appendix D

EDGAR H. HAUG, ESQ.
KEVIN MURPHY, ESQ.
JEFFREY A. HOVDEN, ESQ.
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, New York 10151
(212) 588-0800

Attorneys for Defendants-Appellants Alphapharm Pty., Ltd. and Genpharm, Inc.

December 22, 2008

STATEMENT OF COUNSEL

Based on my professional judgment, I believe the panel decision is at least contrary to the following decisions of this Court: *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995) and *State Industries, Inc., v. A.O. Smith Corp.*, 751 F.2d 1226, 1238 (Fed. Cir. 1985). The panel decision also renders nugatory 35 U.S.C. § 282 and Rules 26 through 37 of the Federal Rules of Civil Procedure for patent challengers. More broadly, the panel's affirmance violates Alphapharm's right to due process. U.S. Const., amend. V; *BMW of N. Am. v. Gore*, 517 U.S. 559, 573 (1996).

If the panel decision is left to stand as it is, it will turn Hatch-Waxman litigation on its head and disturb

the delicate balance Congress intended between the brand and generic drug industries. This appeal therefore requires an answer to one or more precedent-setting questions of exceptional importance:

1. May a court properly sanction a patent challenger who relies on prior art whose relevance was first timely revealed in discovery and admitted into evidence by the district court?

2. In a Hatch-Waxman case, must a patent challenger in a presuit notice provide not only a detailed basis that a patent is invalid, but also address potential affirmative defenses such as lack of commercial success?

Dated: December 22, 2008

By: Kevin Murphy, Esq.
Attorney of Record for
Defendants-Appellants
Alphapharm Pty., Ltd. & Genpharm Inc.

I. POINTS OF LAW AND POLICY IGNORED BY THE PANEL

A. The Panel's Errors

Alphapharm petitions for rehearing en banc of the panel decision affirming the district court's award of attorney and expert fees in the amount of $5.4 million against Alphapharm. The affirmance profoundly

changes the law of this Circuit and shifts the balance Congress carefully crafted between a generic challenger and a brand patentee in a Hatch-Waxman case-to the benefit of the patentee. The affirmance cannot and should not go undisturbed.

Specifically, the district court found that Alphapharm"s pre-litigation statutory Notice of Certification Letter (the "Notice") was baseless and further found Alphapharm to have committed litigation misconduct, concluding that Alphapharm should have "simply pursued the theories presented in" its Notice. (JA30.) This has never been the law. *See, e.g., Pfizer, Inc. v. Teva Pharms. USA, Inc.*, No 04-754, 2007 WL 4300155, at *7-11 (D.N.J. Dec. 5, 2007) (rejecting notion that a notice letter was submitted in bad faith for failing to identify all prior-art references relied on at trial). A case is not suddenly "exceptional" because a party relies on discovery to support its invalidity defense at trial. The award amounts to a changing of the rules in the middle of the game, and violates Alphapharm's right to due process. *Cf. BMW of N. Am.*, 517 U.S. 573 at 573 (prohibiting Alabama jury from imposing punitive sanctions on conduct lawful in other jurisdictions).

The panel appeared to take no position on the district court's clear error, noting that the district court did not "fault [] Alphapharm ***simply*** for changing its obviousness argument at trial from the theory advanced in the Paragraph IV letter." Slip Op. at 8 (emphasis added). Moreover, because the district court never specified what it was about Alphapharm's conduct that

defiled the "temple of justice", the panel ignored the standard in *Amsted Indus. v. Buckeye Steel Castings Co.*, 23 F.3d 374, 378 (Fed. Cir. 1994), in upholding the award of expert fees. The panel had a duty to vacate an exceptional-case finding when that finding rests on ***any*** legally improper grounds. *See Molins*, 48 F.3d at 1186 (remanding for additional findings after accepting as proper some but not all grounds for exceptional-case-finding). Exceptional-case findings must "not [] be an ordinary thing." *State Indus.*, 751 F.2d at 1238 (reversing award of attorneys' fees).

* * * *

APPENDIX E — EXCERPTED DEPOSITION OF HOWARD ROSENBERG DATED MARCH 30, 2005

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

No. 04-cv-1966
(DLC)

TAKEDA CHEMICAL INDUSTRIES, LTD., and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Plaintiffs,

vs.

ALPHAPHARM PTY, LTD., and GENPHARM, INC.,

Defendants.

Confidential – Attorneys' Eyes Only

March 30, 2005

9:01 a.m.

Continued deposition of HOWARD ROSENBERG, held at the offices of Edwards & Angell, 750 Lexington Avenue, New York, New York, before Laurie A. Collins, a Registered Professional Reporter and Notary Public of the State of New York.

Appendix E

[245] * * *

Q. Do you agree or disagree that of the compounds which had been disclosed prior to the filing of the application for the '777 patent the compound shown at the bottom of page 1 of the information disclosure statement is the compound which bears the closest structural similarity to pioglitazone?

MR. MURPHY: Objection.

A. I can't agree with that a hundred percent because the prior art shows simple pyridine as well, and I would include those as well as this particular compound as closest prior art.

Q. When you say "simple pyridine," do I understand you correctly to mean unsubstituted pyridine?

[246] A. In the prior art as I understand it, there was an example of a simple pyridine with no substitution. But there was also claims to a pyridine with substitution, although not exemplified.

Q. What prior art were you referencing in your prior answer?

A. As I understand it, the other patents that resulted out of the '200 patent.

Q. What patents were those?

A. I think it's the '605 patent I need to check it.

Q. Is it your understanding that what you've referred to as the '605 patent is a Takeda patent?

A. I think so.

Q. And do you know when that patent issued?

A. I think — unless you show me, I can't give you a date. But I understand it's a division of the '200. There were two sevens patents that came out, if I remember rightly — I can't remember, but maybe '779 — and shows the compound at the bottom of the page here we're referring to. [247] I have the impression the other patent, '605, has claimed the straight pyridine but in the first claim includes — it generalizes alkyl substitution but does not exemplify.

* * * *

APPENDIX F — EXCERPTED DEPOSITION OF BARRY SPENCER DATED MAY 5, 2005

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CONFIDENTIAL

No. 04-cv-1966
(DLC)

TAKEDA CHEMICAL INDUSTRIES, LTD., and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Plaintiffs,

vs.

ALPHAPHARM PTY, LTD., and GENPHARM, INC.,

Defendants.

May 5, 2005

9:47 a.m.

Deposition of BARRY SPENCER, held at the offices of Edwards & Angell, 750 Lexington Avenue, New York, New York, pursuant to Rule 30 (b) (6) before Laurie A. Collins, a Registered Professional Reporter and Notary Public of the State of New York.

Appendix F

* * *

[36] Q. 71. My mistake.

Let me ask you, is there any basis upon which defendants or any of them contend or will contend that the '777 patent is invalid, unenforceable or will not be infringed which is not contained in Exhibit 15?

A. What I would like to add, what Alphapharm would like to add, is that in — as [37] part of the review of the prior art specifically the Sohda article 1982 and the '200 patent and the file history thereof and the '777 file history or prosecution history, basically in looking at these — If I can give just a bit of a run-through.

* * * *

APPENDIX G — EXCERPTED PLAINTIFFS' OPENING PRE-TRIAL MEMORANDUM OF LAW AND COMBINED PRE-TRIAL SUBMISSIONS WITH RESPECT TO THE '777 PATENT DATED NOVEMBER 18, 2005

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Civil Action No. 03 CV 8250 (DLC)
03 CV 8253 (DLC)
03 CV 8254 (DLC)
04 CV 1966 (DLC)
(Consolidated for trial)

Honorable Denise L. Cote

Takeda Chemical Industries, Ltd., and Takeda Pharmaceuticals North America, Inc.,

Plaintiffs,

v.

Ranbaxy Laboratories, Ltd., et al.,
Mylan Laboratories, Inc., et al.,
Watson Pharmaceuticals, Inc., et al.,
Alphapharm Pty, Ltd., et al.,

Defendants.

PLAINTIFFS' OPENING PRE-TRIAL MEMORANDUM OF LAW AND COMBINED PRE-TRIAL SUBMISSIONS WITH RESPECT TO THE '777 PATENT

Appendix G

* * *

IV. SECONDARY CONSIDERATIONS ALSO DEMONSTRATE NON-OBVIOUSNESS

Without Alphapharm having proved a prima facie case of obviousness, there is no need for this Court to consider objective evidence of non-obviousness. Nevertheless, were that evidence considered, it would strongly overcome any such prima facie case and establish non-obviousness. The so-called "secondary considerations" include: (1) the extent of commercial success of the patented invention; (2) unexpected properties of the invention compared to the "closest" prior art; (3) whether the invention satisfies a long-felt need; (4) whether others have failed to find a solution to the problem solved by the invention; and (5) copying of the invention by others. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966). Skepticism by those skilled in the art, and industrial acclaim, are also factors. Monarch Knitting Machinery Corp. v. Sulzer Morat GMBH, 139 F.3d 877, 855 (Fed. Cir. 1998) (skepticism); Heidelberg Harris v. Mitsubishi Heavy Indus. Ltd., Nos. 99-1100, 99-1101, 99-1102, 2000 WL 1375270, at 11 (Fed. Cir. Sept. 18, 2000) (industrial acclaim). Although Takeda bears the burden of coming forward with rebuttal evidence showing facts supporting non-obviousness, it remains Alphapharm's burden to prove by clear and convincing evidence that these objective factors point to obviousness.

* * * *